4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0754]

# Pediatric Medical Devices; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until March 5, 2012, the comment period for the notice entitled "Pediatric Medical Devices; Public Workshop; Request for Comments" that appeared in the Federal Register of Tuesday, November 1, 2011 (76 FR 67463). In the notice, FDA announced a public workshop to consider factors affecting the use of scientific research data to support pediatric medical device efficacy claims. This is part of an on-going effort to address the ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling. The agency is taking this action to allow interested persons additional time to submit comments on the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.

DATES: Submit either electronic or written comments by March 5, 2012.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

## I. Background

In 2007, Congress passed the Pediatric Medical Device Safety and Improvement Act (the Act). The Act addresses pediatric device needs by providing financial incentives for development, production, approval and distribution of new devices for rare and unmet pediatric needs; allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device; and providing grants to pediatric device consortia that provide technical support and assistance to pediatric device innovators.

FDA held a public workshop on December 5, 2011, to support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research

data. An important, but not the only, focus was a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations.

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices treat or diagnose diseases and conditions occurring from birth through the 21st year of life. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Designing pediatric medical devices can be challenging; children are often smaller and more active than adults; body structures and functions change throughout childhood, and children may be long-term device users--bringing new concerns about device longevity and long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

Regardless of attendance at the public workshop, interested persons may submit either electronic or written comments on the topics discussed at the Public Workshop.

## II. Topics Discussed at the Public Workshop

The public workshop discussed the following topic areas:

1. The use of existing scientific research data to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance,

2. The scientific and regulatory limitations and issues with the use of existing scientific research data, and

3. The methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

## III. Transcripts

Please be advised that a transcript of the public workshop is available at http://www.regulations.gov at FDA docket number FDA-2011-N-0754. The transcript may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript is also available online at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm.

## IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 19, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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